

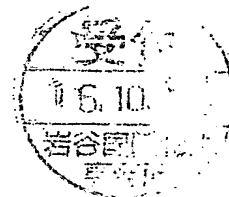
From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 72.2)

To:

Rec'd PCT/PTO 15 FEB 2005

IWATANI, Ryo
Sakurabashi Chiyoda Build. 5F
1-27, Dojima 2-chome, Kita-ku
Osaka-shi, Osaka 530-0003
JAPON

| | |
|---|--|
| Date of mailing (<i>day/month/year</i>) 14 October 2004 (14.10.2004) | |
| Applicant's or agent's file reference DS07F927 | IMPORTANT NOTIFICATION |
| International application No. PCT/JP2002/013879 | International filing date (<i>day/month/year</i>) 27 December 2002 (27.12.2002) |
| Applicant SUNTORY LIMITED et al | |

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, CN, EP, KR

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AU, BR, IL, JP, US

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsimile No. +41 22 740 14 35

Facsimile No. +41 22 338 70 10

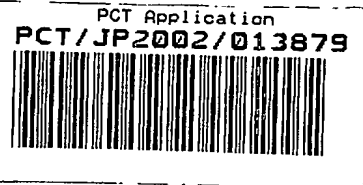
Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Rec'd PCT/PTO 15 FEB 2005

| | | |
|--|---|--|
| Applicant's or agent's file reference DS07F927 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/JP02/13879 | International filing date (day/month/year) 27 December 2002 (27.12.02) | Priority date (day/month/year) 09 January 2002 (09.01.02) |
| International Patent Classification (IPC) or national classification and IPC C12N 15/54, 15/12, 9/10, C07K 14/515, A61K 38/17 | | |
| Applicant SUNTORY LIMITED | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand 12 June 2003 (12.06.03) | Date of completion of this report 31 October 2003 (31.10.2003) |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP02/13879

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP02/13879

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 14-18

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 14-18
are so unclear that no meaningful opinion could be formed (*specify*):

See supplemental sheet

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14-18

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

With regards to the compounds set forth in claims 14, 17 and 18, the description (page 38) sets forth only the compound DFK167, and does not specifically set forth any other compounds; thus, it is unclear what substances other than DFK167 are included within the scope of said compounds. Therefore, the disclosures of the aforementioned claims are extremely unclear, and consequently it is impossible to conduct a meaningful international search in relation thereto.

In addition, with regards to the compounds set forth in claims 15 and 16, even with consideration of the disclosures in the description it is unclear specifically what compounds are included and what compounds are not included in the scope thereof; thus, the disclosures of claims 15-17 are unclear. Therefore, it is impossible to conduct a meaningful international search in relation thereto.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 02/13879

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|--------------|-----|
| Novelty (N) | Claims | 6-13, 19, 22 | YES |
| | Claims | 1-5, 20, 21 | NO |
| Inventive step (IS) | Claims | 6-13, 19 | YES |
| | Claims | 1-5, 20-22 | NO |
| Industrial applicability (IA) | Claims | 1-13, 19-22 | YES |
| | Claims | | NO |

2. Citations and explanations

- Document 1: EP 585109 A2 (Suntory, Ltd.), 02 March 1994
- Document 2: K. MURATA et al., "Expression of N-acetylglucosaminyltransferase V in Colorectal Cancer Correlates with Metastasis and Poor Prognosis," Clin. Cancer Res., 2000, Vol. 6, No. 5, pages 1772-7
- Document 3: K. SASAKI et al., "The Critical Role of the Stem Region as a Functional Domain Responsible for the Oligomerization and Golgi Localization of N-acetylglucosaminyltransferase V," J. Biol. Chem., 2001, Vol. 276, No. 1, pages 759-765
- Document 4: M. S. WOLFE et al., "A Substrate-based Difluoro Ketone Selectively Inhibits Alzheimer's γ -secretase Activity," J. Med. Chem., 1998, Vol. 41, pages 6-9
- Document 5: N. TANIGUCHI et al., "Implication of N-acetylglucosaminyltransferases III and V in Cancer: Gene Regulation and Signalling Mechanism," Biochimica et Biophysica Acta, 1999, Vol. 1455, pages 287-300
- Document 6: JP 9-84582 A (Kirin Brewery Co., Ltd.), 31 March 1997
- Document 7: T. SAITO et al., "A Secreted Type of β 1,6-N-

acetylglucosaminyltransferase V (GnT-V)
Induces Tumor Angiogenesis Without Mediation
of Glycosylation," J. Biol. Chem., 2002,
Vol. 277, No. 19, pages 17002-17008

Document 1 discloses a feature wherein the DNA that codes GnT-V was cloned, and recombinants were expressed using host cells. Consideration of the base sequence of said DNA shows that it includes the amino acid sequence represented by SEQ ID NO: 7 in this application, which is to say, a basic amino acid cluster.

Herein, the invention set forth in claim 1 of this application is a "protein that contains a region wherein basic amino acid sequences are clustered," and thus includes the protein that comprises the entire length of the GnT-V sequence. Consequently, the invention set forth in claim 1 of this application is the same as the invention disclosed in document 1; therefore, it lacks novelty.

In addition, with consideration of the disclosures of claim 1 from document 1, the inventions set forth in claims 2-5 of this application are also the same as the inventions disclosed in document 1; therefore, they lack novelty.

Document 2 indicates the establishment of monoclonal antibodies against GnT-V from humans and the detection of GnT-V using said monoclonal antibodies.

An examination of the abovementioned feature shows that the inventions set forth in claims 20 and 21 of this application are the same as the inventions disclosed in document 2; therefore, they lack novelty.

In addition, it would be common practice for a person skilled in the art to create a kit for conducting detection using said monoclonal antibodies; therefore, the invention set forth in claim 22 of this application does

not involve an inventive step in the light of the invention disclosed in document 2.

Document 3 indicates that the stem region of GnT-V has a function related to binding with a membrane, and that the deletion of said region does not affect the transferase activity of GnT-V.

Document 4 indicates a compound, DFK167, which has a γ -secretase activity.

Document 5 suggests that ets-1, which is a transcription factor, can also bind to the transcription control region of GnT-V and control transcription. In addition, document 5 indicates that said ets-1 is a protein involved in the transcription of the α and β receptors of T cells, the transcription of interleukin 2 β and the like.

Document 6 discloses the feature of producing recombinant cells that can express large amounts of GnT-V.

Even with consideration of the disclosures therein, documents 3-6 do not disclose or suggest a feature wherein the basic amino acid cluster region in GnT-V has an angiogenic action. Specifically, it is possible to infer that ets-1 contributes to the angiogenic action in the light of the disclosures of document 5, but even a person skilled in the art would merely infer that because ets-1 is a transcription factor, it simply adjusts the transcription rate of GnT-V. However, the function wherein GnT-V is cleaved to form a secretor that has an angiogenic action could not have been predicted.

Therefore, the inventions set forth in claims 6-13 and 19 of this application are novel, involve an inventive step, and have industrial applicability.